The Principles of Good Laboratory Practice: Application to *In Vitro* Toxicology Studies

The Report and Recommendations of ECVAM Workshop 37[1,2]

Reprinted with minor amendments from ***ATLA* 27**, 539-577.

Appendix 1

Terminology

These terms are based on the terms contained in the OECD Principles of Good Laboratory Practice. Recommended additions are in bold and underlined.

***Good Laboratory Practice* Good Laboratory Practice (GLP).** A quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

Terms Concerning the Organization a Test Facility

Master Schedule. A compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

Principal Investigator. An individual who, for a multi-site study, acts on behalf of the Study Director and has defined responsibilities for delegated phases of the study. The Study Director's responsibility for the overall conduct of the study cannot be delegated to the Principal Investigator; this includes approval of the study plan and its amendments, approval of the **study** report, and ensuring that all applicable Principles of Good Laboratory Practice are followed.

Quality Assurance Programme. A defined system, including personnel, which is independent of study conduct and is designed to assure Test Facility Management of compliance with these principles of Good Laboratory Practice.

Sponsor. An entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

Standard Operating Procedures (SOPs). Documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.

Study Director. The individual responsible for the overall conduct of the non-clinical health and environmental safety study.

Test Facility. The persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multi-site studies (studies conducted at more than one site), the test facility comprises the site at which the Study Director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

Test Facility Management. The persons who have the authority and formal responsibility for the organization and functioning of the test facility according to these Principles of Good Laboratory Practice.

Test Site. A location at which a phase of a study is conducted.

Test Site Management (if appointed). The person responsible for ensuring that the phase of the study, for which he/she is responsible, are conducted according to these Principles of Good Laboratory Practice.

Terms Concerning the Study

Acceptance Criteria. The basis for determining the acceptability of an assay according to predefined performance parameters.

Experimental Completion Date. The last date on which data are collected from the study.

Experimental Starting Date. The date on which the first study-specific data are collected.

Good Laboratory Practice Compliance Statement. A formal record, signed and dated by the Study Director, to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with Good Laboratory Practice.

Non-clinical Health and Environmental Safety Study. Henceforth referred to simply as "study", is an experiment or set of experiments in which a test **item(s)** is examined under laboratory conditions or in the environment, to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

Quality Assurance Statement. A formal record listing the types of inspections made and their dates, including the phase inspected, and the dates any inspection results were reported to Management, and to the Study Director and Principal Investigator, if applicable. This statement also serves to confirm that the final report reflects the raw data, as appropriate.

Raw Data. All original test facility records and documentation, or verified copies there of, which are the result of the original observations and activities in a study. Raw data can also include photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for the required time-period.

Short-term Study. A study of short duration with widely used, routine techniques.

Specimen. Any material derived from a test system for examination, analysis, or retention.

Study Completion Date. The date on which the Study Director signs the **study** report.

Study Initiation Date. The date on which the Study Director signs the study plan.

Study Plan. A document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

Study Plan Amendment. An intended change to the study plan after the study initiation date.

Study Plan Deviation. An unintended departure from the study plan after the study initiation date.

Study Report. A document which reports the objectives, procedures, results and conclusions of a study. Test System. Any biological, chemical or physical system, or combination thereof, used in a study.

Terms concerning the test, reference and control items

Batch. A specific quantity or lot of a test reference **or control** item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

Control Item. An article used to monitor the performance of an assay, which might not necessarily be used in the same manner as a reference item. **Reference Item.** Any article used to provide a basis for comparison with the test item.

Test Item. An article that is the subject of a study.

Vehicle. Any agent which serves as a carrier used to mix, disperse, or solubilise the test, reference **or control** item to facilitate the administration/application to the test system.

Terms covering prevalidation and validation

Prevalidation Study. A study carried out following test development, but prior to the possible inclusion of a test in a formal validation study. This need not. but usually does. include the blind testing of coded chemicals.

Validation. The process by which the reliability and relevance of a procedure are established for a specific purpose. The main goal is to conduct multi-site trials with coded test items. as a basis for assessing whether one or more tests. test batteries or testing strategies can be shown to be relevant and reliable for one or more specific purposes. according to Redefined performance criteria.

Terms concerning multi-study trials

Multi-study Trial. A set of studies which can be used to compare methods and/or test item(s) and generally refers to prevalidation/validation studies. Trial Coordinator. The individual who coordinates the overall conduct and reporting of a multi-study trial.

Trial Management Team. The persons who have responsibility for overseeing the organization. conduct and reporting of a multi-study trial.

Trial Plan. A document which outlines the goals. design. participants and proposed time-scales of the multi-study trial.

Trial Report. The document which summarises the goals, procedures, results and conclusions of a multi-study trial.